iHealth®

Align Gluco-Monitoring System (BG1)
OWNER'S MANUAL

For in vitro diagnostic use only

Read instructions before use for self-testing

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INTRODUCTION

Thank you for purchasing the iHealth Align Gluco-Monitoring System (BG1). This manual provides important information to help you use the system properly. Before using this product, please read the Owner's Manual thoroughly. Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to the meter's compact size and simple operation, you can easily self-monitor your blood glucose levels anywhere, anytime. If you have questions regarding this product, please visit www.ihealthlabs.com, contact your place of purchase, or call iHealth Labs Customer Service at 1-855-816-7705.

INTENDED USE

The iHealth Align Gluco-Monitoring system (BG1) is intended to be used for:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh.
- Single person measurement (it should not be shared).
- Self-testing outside the body (in vitro diagnostic use) as an aid to monitor the effectiveness of diabetes control.

The iHealth system should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

- Alternative Site Testing (AST) should be performed only during steady state times when glucose levels are not changing rapidly.
- iHealth Blood Glucose Test Strips(AGS-1000I) are intended for use with the iHealth Align Gluco-Monitoring System to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.
- The iHealth control solutions are intended for use with the iHealth Align Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.
- The iHealth Gluco-Smart App is the iOS application for the iHealth Gluco-Monitoring System, and is used for data extraction and analysis.

COMPATIBILITY

The iHealth system is compatible with select iOS and Android devices. For a complete list of compatible devices, visit our support page at www.ihealthlabs.com.

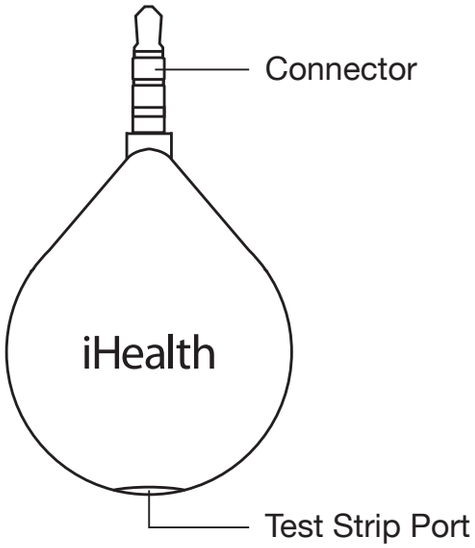
IMPORTANT SAFETY INSTRUCTIONS

Please read the following information carefully before using the iHealth system. Always keep these instructions in a safe place for reference.

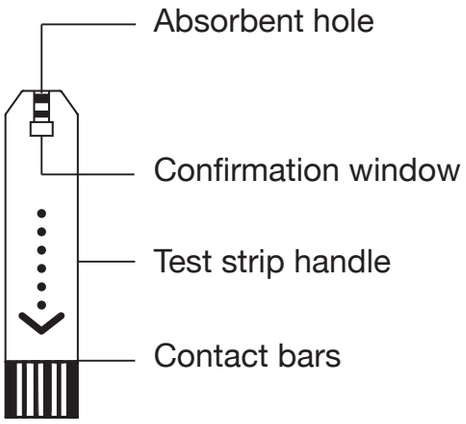
- Misuse of the iHealth system can cause electrocution, burns, fire, and other hazards.
- The glucose meter and lancing device are for single patient use. Do not use either item on multiple patients.
- Do not share the glucose meter or lancing device with anyone, including other family members.
- Do not place the iHealth system in or near liquid.
- Use the iHealth system only for the purpose described in the Owner's Manual.
- Use only iHealth branded accessories.
- Do not use the iHealth system if it has sustained any damage or is not working properly.
- Keep the iHealth system away from heat at all times. Do not let the iHealth system come into contact with surfaces that are hot to the touch.
- Do not block test port or place the glucose meter on soft surfaces that may block the test port. Keep test port free from lint, hair, debris, etc.
- Do not place anything on top of the glucose meter.
- Do not place foreign objects into any opening in the glucose meter.
- Do not use the glucose meter in a manner not specified by the manufacturer.
- When not in use, please disconnect the glucose meter from the mobile device.
- All parts of the iHealth system are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Please refer to the resources identified below for detailed information:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

PARTS AND DISPLAY

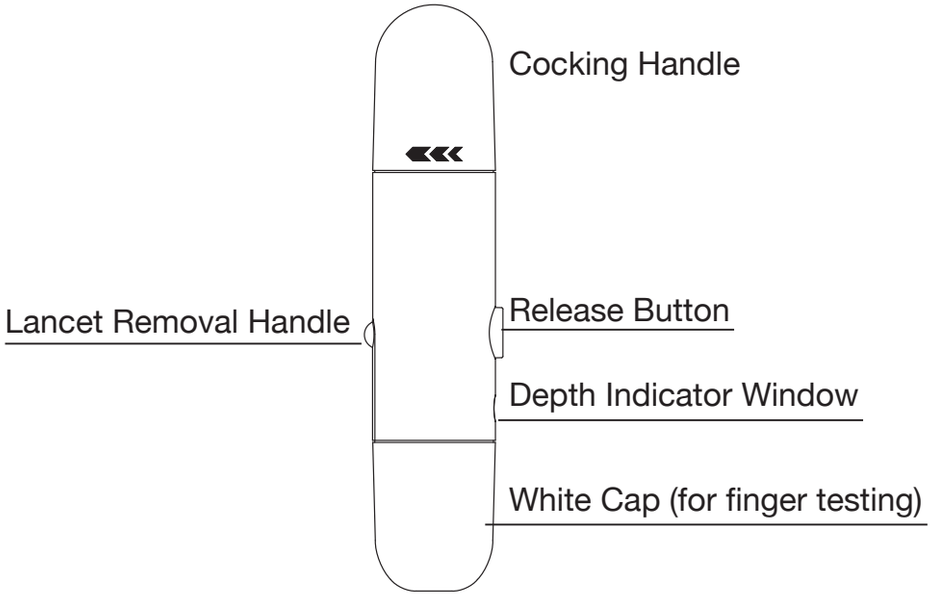


• **The Meter**

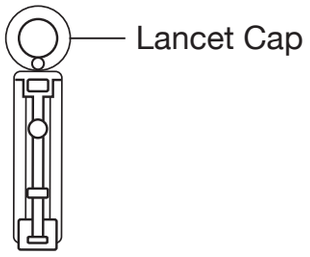


• **The Test Strip (AGS-1000I)**

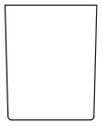
• **iHealth Control Solution (Level II)**



• **iHealth Lancing Device**



• **Lancet**



• **Clear Cap for Alternate Site Testing**

Note:

1. If any items printed on the package are missing from your package or the package appears to have been opened prior to your use, please call iHealth Labs Customer Service at 1-855-816-7705.

2. The lancing device can be used multiple times, however, the lancet should be changed after each use.

3. The number of sanitary covers for the mobile device is equal to the number of test strips.

4. Only iHealth Level II control solution is included in the package.
If you need level I and level III control solution, please call iHealth Labs Customer Service at: 1□855□816□7705 for assistance.

5. Content may vary according to geographic markets. Please check your package.

Mobile Device Compatibility

The iHealth system is compatible with select iOS and Android devices. For a complete list of compatible devices, visit our support page on www.ihealthlabs.com.

TEST PRINCIPLE

Testing with the iHealth system is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the test strip. The iHealth system measures the current and converts it to the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

IMPORTANT TEST INFORMATION

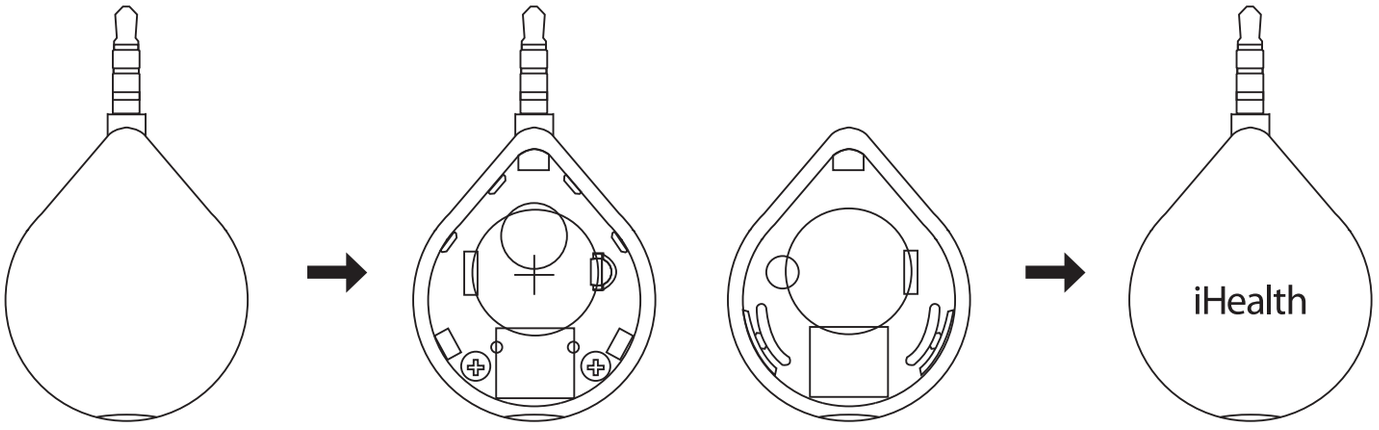
- Severe dehydration or excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult your healthcare professional before use.
- If your blood glucose results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results that are higher or lower than usual, follow the treatment advice of your healthcare professional.

- If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all of the instructions provided in this Owner's Manual, contact your healthcare professional immediately.
- Use only fresh whole blood samples to test your blood glucose.
- Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- Always use care when handling the iHealth Align Glucose Meter. Dropping or throwing the meter may cause damage.
- Don't expose the iHealth Align Glucose Meter, test strips, or control solution to extreme conditions such as high humidity, heat, freezing cold, or dust.
- The lancing device is for self-use only. Do not share or re-use lancets. Please refer to the Lancing Device Manual for the detailed procedure.

INSTALL THE BATTERY

Your meter comes with two 3V CR1620 lithium batteries. Follow the instructions below to install the battery.

1. Turn the meter over with the iHealth logo facing down.
2. Lift off the back cover by pulling firmly from the notch next to the test strip port.
3. Insert the new battery with the "+" side facing up and snap it into the battery tray.
4. Press the back panel back in place by inserting the front clip into place first before snapping the back panel down.



When the “Battery is low” indicator appears on the app, replace the battery to ensure successful and accurate measurements.

Disposal – Electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

GET STARTED

- **Download the App**

  Prior to first use, download the free iHealth Gluco-Smart App to your mobile device from the Apple App Store or Google Play Store. Follow the on-screen instructions to create your iHealth account.

- **Access the iHealth Cloud Account**

  Your iHealth account also gives you access to the free and secure iHealth cloud service. Go to www.ihealthlabs.com and click “Sign In” for access once your account has been created.

- **Test blood glucose level**

  Step 1: Launch the App

  Step 2: Connect the meter

  - Plug your meter into the headphone jack of your mobile device. The iHealth logo on the meter should be facing the same direction as the screen of your mobile device.
  - Allow microphone access when prompted.

  Note:

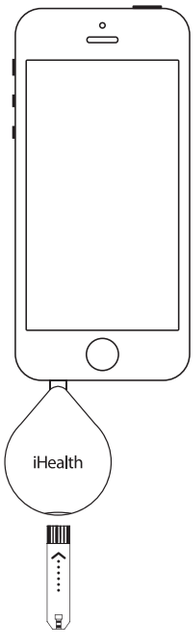
  - *Do not twist your meter during the measurement process.*
  - *You might need to remove the case on your mobile device before connecting the meter.*

  Step 3: Scan to Code the Test Strips

  Please carefully read and follow the instructions below to avoid getting inaccurate readings: **Scan the QR code on the top of the iHealth test strip vial to calibrate the test strips with the meter. You must scan the QR code ONLY when a new vial is opened for the first time.**

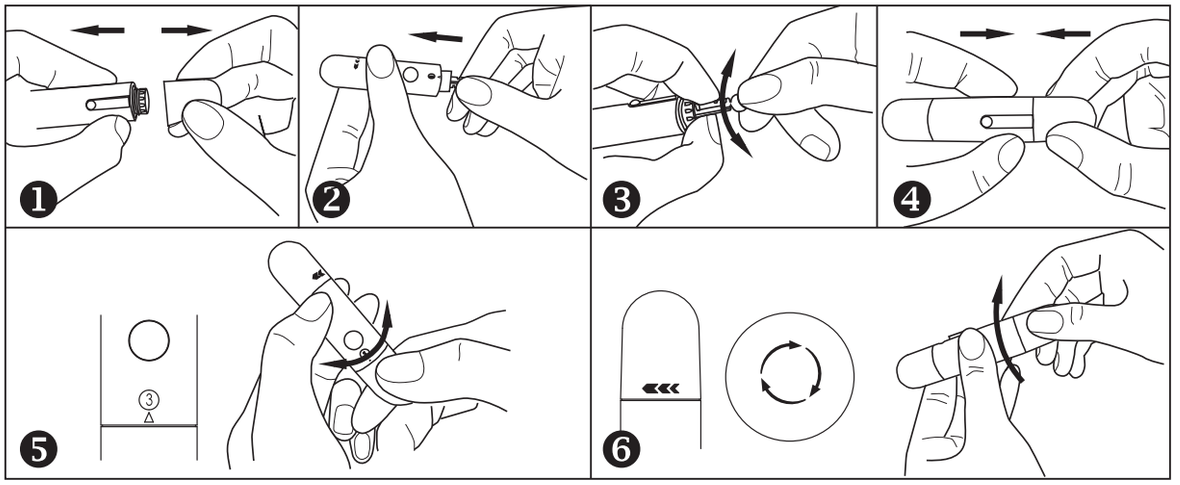
  Step 4: Insert the test strip into the meter’s strip port

  Make sure the red arrow marker on the test strip is facing the same direction as the iHealth logo on the meter.



Step 5: Prepare the lancing device

❶ Snap off the lancing device cap
❷ Insert a new lancet firmly into the lancing device holder cup
❸ Twist the lancet cover off
❹ Replace the lancing device cap
❺ Set the lancing level to your desired pressure level
❻ Cock the handle until it clicks

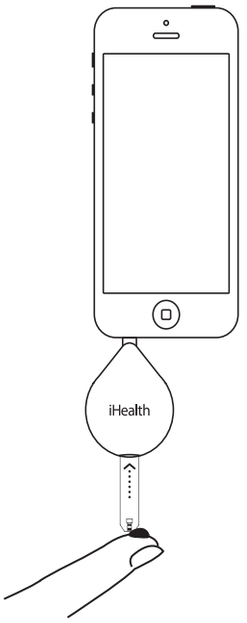


Step 6: Obtain a blood sample

Press the lancing device against the site to be lanced and then press the release button to puncture the site. Gently squeeze the site until a drop of blood forms.

Step 7: Apply the blood sample to the test strip

Quickly apply the blood sample to the absorbent hole on the tip of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample, and remove your finger.



Step 8: Read the test results

After approximately 5 seconds, your blood glucose result will appear on your mobile device screen. The meter needs to remain connected to your mobile device during testing and syncing.

Note:

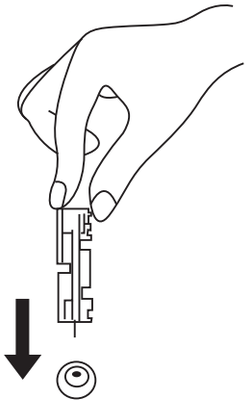
The results obtained from the glucose meter are plasma-calibrated. This helps you and your physician or other qualified healthcare providers to compare your meter results with laboratory tests. Refer to the instructions given by your physician or other qualified healthcare providers. Do not deviate from these instructions on the basis of the result without first consulting your physician.

Step 9: Discard the used test strip and lancet

Remove the used test strip from the meter using a tissue.

Remove the lancet from the lancing device. (Tip: Prior to disposal, stick the lancet into the cover that was snapped off earlier in the process.)

Discard the used test strip and lancet properly.

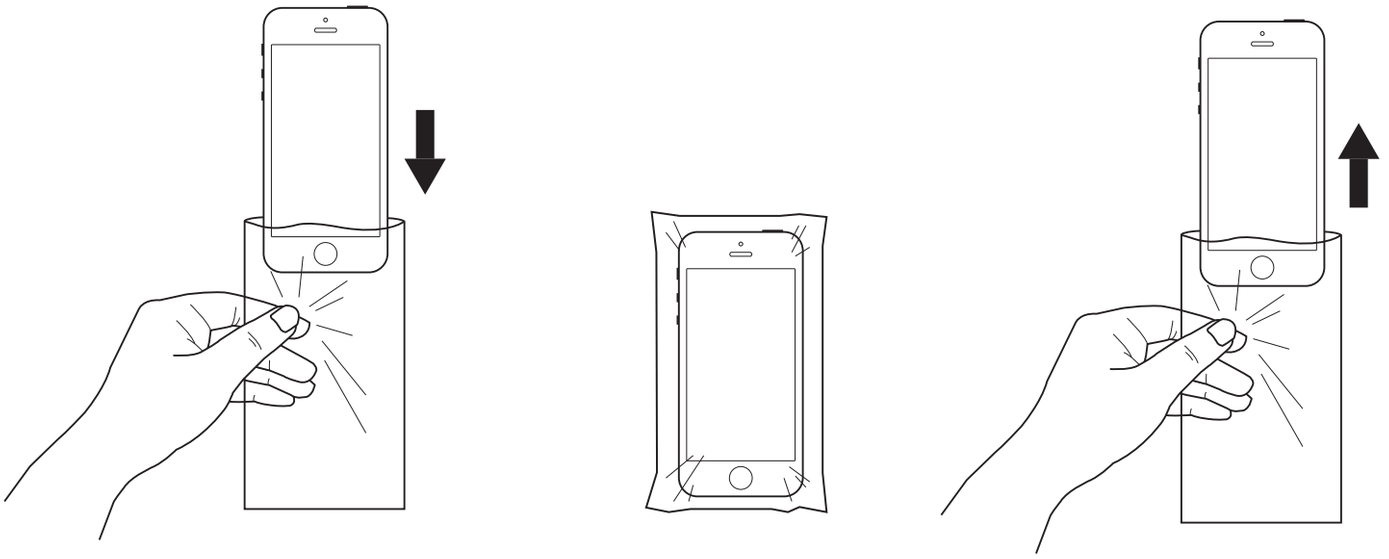


Note:

Refer to the Cleaning and Disinfecting section of the Owner's Manual for cleaning and disinfecting procedures.

USING PHONE SANITARY COVER

We strongly advise that you put your mobile device into the sanitary cover before testing. The sanitary cover is for single testing use only. Please contact iHealth customer service for purchasing additional sanitary covers.



REFERENCE VALUE OF THE iHealth Align GLUCO-MONITORING SYSTEM

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: American Diabetes Association: Diagnosis and Classication of Diabetes Mellitus (Position Statement). Diabetes Care 36 (Supp. 1) S71, 2013.

Please consult a healthcare professional for interpretation of your blood glucose measurements and to determine a target range that is best for you.

THE IHEALTH SYSTEM CARE AND MAINTENANCE

- Always use care when handling the iHealth Align Glucose Meter. Dropping or throwing the meter may cause damage.
- Don't expose the iHealth Align Glucose Meter, test strips, or control solution to extreme

conditions such as high humidity, heat, freezing cold, or dust.

Cleaning And Disinfecting the Meter and Lancing Device

The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can ensure the meter works well (for example, display will be clear to see after cleaning); and disinfection will reduce the chance of spreading infection to others.

The meter and lancing device should be cleaned and disinfected following each use. We suggest that you use CaviWipes™ (Metrex® Research Corporation, EPA Reg. No. 46781-8, EPA Est. No. 56952-WI-001). CaviWipes, with isopropanol and diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredients, have been shown to be safe for use with the meter and lancing device.

You can purchase this product from the suppliers listed below:

(1) Visit the website www.metrex.com or contact Metrex at 800-841-1428 for product or technical information.

(2) Visit the website http://www.endochoice.com/Equipment?search=wipe.

The meter and lancing device are validated to withstand 11,000 individual tests and 11,000 cleanings over their 5-year life spans.

Steps for cleaning and disinfecting the meter and lancing device

1. After a test, clean and wash your hands.
2. Use one CaviWipe to carefully clean the meter, front and back.
3. Disinfect the meter with another wipe and let it air dry.
4. Use the same method with the CaviWipes to clean and disinfect the lancing device.
5. Take off and discard the sanitary cover for the mobile device after each test.

WARNING

① Each disinfection step requires a pre-cleaning step. Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

② Only the surface of the meter can be cleaned and disinfected with the disinfecting towelette. Do not insert the CaviWipe into the test port.

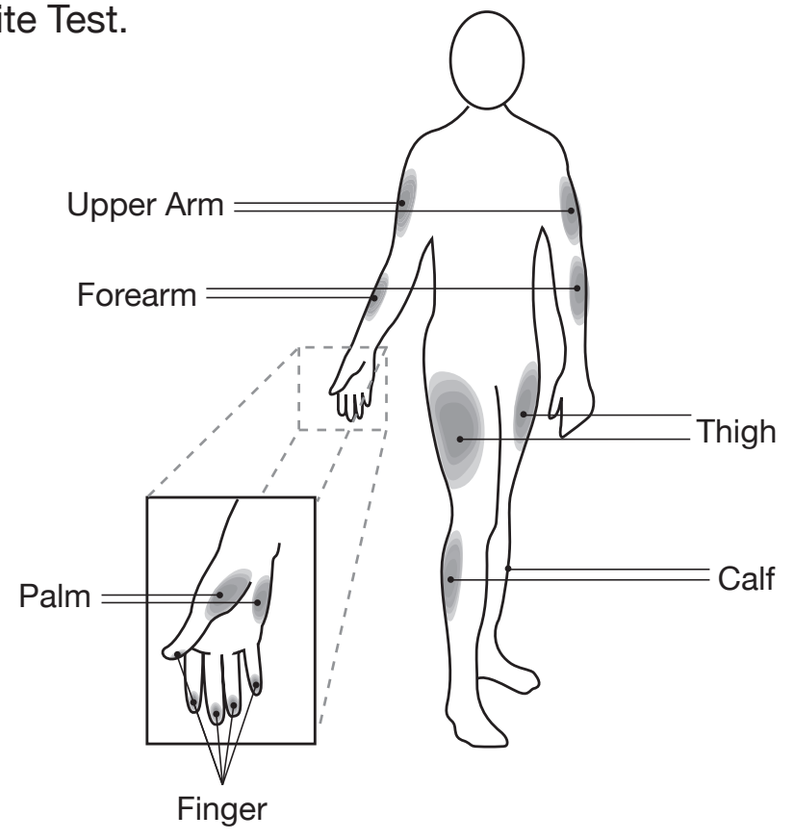
Signs of Potential Physical And Performance Deterioration

If you encounter any of the following circumstances, stop using the meter and contact the place of purchase for assistance, or call the iHealth toll free customer service number at 1-855-816-7705:

1. The device does not work; for example, the mobile device does not begin testing when the meter is connected with the mobile device and when a test strip is inserted into the meter.
2. Discoloration of the meter casing or lancing device; for example, it is difficult to read the labeling information.
3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the meter casing or lancing device.

PERFORMING A BLOOD GLUCOSE TEST WITH ALTERNATE SITE

You have the option of taking a blood sample from other sites on your body besides the fingertip. The iHealth system allows you to test on your palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing when used appropriately. Remember to replace the lancing device cap with the clear cap and follow the above “Test blood glucose level” instructions to perform an Alternate Site Test.



Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood from the fingertips reflects these changes faster than capillary blood from other sites. AST should be used only during steady-state times when blood glucose levels are not changing rapidly. You may perform Alternate Site Testing in the following instances:

• In a pre-meal or fasting state (two hours or more after the last meal).
• Two hours or more after taking insulin.
• Two hours or more after exercising.

• Two hours or more after exercising.

You should NOT perform AST if:
• You think your blood glucose is low.
• You are unaware that you might have hypoglycemia.
• You are testing for hyperglycemia.
• Your AST results do not match the way you feel.
• Your routine glucose results fluctuate often.

Caution: Alternate Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs). Results from Alternate Site Testing should not be used in insulin dose calculations.

IMPORTANT INFORMATION ABOUT CONTROL SOLUTION TESTS

The control solution contains a known amount of glucose that reacts with test strips and is used to check that your meter and test strips are working together properly. The result of the control solution test should be within the range printed on the test strip vial label.

Materials needed to perform a control solution test:
• iHealth Align Gluco-Monitoring System (BG1)
• iHealth Blood Glucose Test Strip（AGS-1000I）
• iHealth Control Solution (Level I, Level II, or Level III)

Perform a control solution test when:
• First receiving or purchasing the meter.
• Checking the meter and test strips (which should be done at least once a week).
• Using a new vial of test strips.
• You suspect the meter and/or test strips are not working properly.
• Your blood glucose test results are not consistent with your expectations, or you think the results are not accurate.
• Practicing the testing process.
• After the test strips are exposed to extreme conditions.

• The meter has been dropped or damaged.

Performing a control solution test

When the meter is connected to your iHealth Gluco-Smart App on your mobile device:

Step 1: Launch the app.

Step 2: Tap the CTL button to switch to control (CTL) mode.

Step 3: Apply the control solution.

• Shake the control solution vial before each use.

• Squeeze a drop of control solution into the vial cap. For better results, it is recommended that you use the second drop of the control solution (discard the first drop).

• Hold the meter and move the absorbent hole of the test strip to catch the drop. Once the confirmation window fills completely, the app display will start counting down. Remove the control solution sample from the test strip when the countdown begins.

Note: To avoid contaminating the entire vial of control solution, do not directly apply control solution onto a strip.

Step 4: Read and compare the results.

After the app display counts down to “1,” the control solution test result will appear on it.

The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test.

Out-of-Range Results

Results falling outside the specified range may be caused by:

• Error in performing the test.

• Expired or contaminated control solution.

• Expired or contaminated test strip.

• Meter malfunction.

If you continue to get control solution test results that fall outside of the range printed on the vial, the meter may not be working properly. Discontinue use and call iHealth Labs Customer Service at 1-855-816-7705 for assistance.

To purchase additional control solution, call iHealth Labs Customer Service.

NOTE:

• *Do not use expired control solution.*

• *The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.*

COMPARING GLUCOSE METER TEST RESULTS WITH LABORATORY RESULTS

The iHealth system provides you with whole blood equivalent results. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation. The iHealth system results can be affected by factors and conditions that do not affect laboratory results in the same way.

To make an accurate comparison between the iHealth system and laboratory results, follow the guidelines below.

Before the Lab Test

- Perform a control solution test to make sure that the meter is working properly.
- If possible, fast at least eight hours before conducting a comparison test.
- Take the iHealth system with you to the lab.

While at the Lab

Make sure that samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your glucose meter with blood samples collected in a test tube.
- Use fresh capillary blood only.

iHealth Align GLUCO-MONITORING SYSTEM SPECIFICATIONS

1. Model: BG1
2. Machine size: 2.03”× 1.17”× 0.37” (52mm × 30mm × 9.5mm)
3. Measuring method: Amperometric technology using glucose oxidase
4. Result range: 20 mg/dL - 600 mg/dL (1.1 mmol/L - 33.3 mmol/L)
5. Power source: DC3.0V (CR1620)
6. Storage condition: Test Strips 39.2° F - 86° F (4° C - 30° C), Humidity 10% - 80% RH
7. Storage condition: The meter -4° F - 131° F (-20° C - 55° C); Humidity 10% - 80% RH
8. Operating conditions: 50°F - 95°F (10° C - 35° C)
9. Blood source: Fresh capillary whole blood
10. Blood Sample Size: Min. 0.7 microliter
11. Product life span: Five years
12. The table of substances below shows the highest concentration without significant interference (± 10% error).

Compounds	Limitation
Ascorbic acid	2mg/dL
Uric acid	＞10mg/dL
Acetaminophen	＞5mg/dL
Bilirubin	＞15mg/dL
Dopamine	＞0.03mg/dL
L-dopa	＞0.45mg/dL
Methyldopa	＞0.75mg/dL
Tolbutamide	＞24mg/dL
Triglycerides	＞2000mg/dL
Hemoglobin	＞250mg/dL

LIMITATIONS OF USE

- The iHealth Align Gluco-Monitoring System is not intended for use on neonates.
- The iHealth Align Gluco-Monitoring System is not intended for use on artery blood, serum, plasma and venous blood samples.
- The iHealth Align Gluco-Monitoring System should only be used with iHealth test strips (AGS-1000I).
- The iHealth Align Gluco-Monitoring System can be used up to an altitude of 10,744 feet (3,276 meters).
- The following substances at levels greater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%), resulting in an inaccurate result: ascorbic acid, uric acid, acetaminophen, dopamine, L-dopa. These substances do not affect test results in normal concentrations but may affect test results in high concentrations. Do not use haemolysis samples, icterus samples, or high lipemia samples.
- Patients undergoing oxygen therapy may show results lower than actual levels.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Red blood cell count (hematocrit) extent 20%-60% can lead to incorrect test results.If you do not

comparison of the iHealth system to another monitoring system known to be well maintained and monitored by a healthcare provider.

- The meter will automatically adjust for the current time zone when the testing takes place. When traveling across time zones, living on or near a time zone boundary, you need to be aware that the logged glucose measurement times may not be synchronized to your normal day-to-day regime.
- If you take insulin and will be traveling across time zones, talk to your health care professional before

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call iHealth Labs Customer Service at 1-855-816-7705. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.

Problems	Possible Causes	Solution(s)
The meter does not respond after the test strip has been inserted into the glucose meter.	1. The meter is not correctly connected to a mobile device.	1.Remove the meter from the mobile device and reconnect.
	2. Too much time has passed between inserting the test strip and performing the test.	2. Remove and reinsert the test strip into the glucose meter.
	3. Test strip has not been fully inserted into the glucose meter.	3. Reinsert the test strip into the glucose meter.
Test results are inconsistent or control solution test results are not within the specified range.	1. Not enough blood sample in the test strip.	1. Retest with a new test strip and make sure that enough sample has been applied.
	2. Test strip or control solution has expired.	2. Retest with a new test strip or new control solution.
	3. Test strip has been damaged due to heat or humidity.	3. Perform a control solution test using a new test strip. If results are still out of range, replace with new vial of test strips.
	4. iHealth System is not performing due to the environment being above or below room temperature.	4. Bring the iHealth System to room temperature environment and wait approximately 30 minutes before performing a new test.

After blood sample has been applied to the test strip, testing doesn't start.	Test strip is not inserted properly.	Use a new test strip and redo the test.

WARRANTY INFORMATION

iHealth Lab, Inc. ("IHealth") warrants the iHealth meter (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of three years from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these are the sole and exclusive remedies. For more information, please visit www.ihealthlabs.com or contact customer service.

iHealth is a trademark of iHealth Lab Inc.
"Made for iPod," "Made for iPhone" and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone or iPad may affect wireless performance. iPod Touch, iPhone, and iPad are trademarks of Apple Inc., registered in the U.S. and other countries.

Manufactured for iHealth Lab Inc.

USA:
iHealth Lab Inc. www.ihealthlabs.com
Mountain View, CA 94043, USA
+1-855-816-7705
(8:30 AM – 5:30 PM PST, Monday to Friday except holidays)
Email: support@ihealthlabs.com

If you have questions or need assistance outside the operational days and times, please contact your health care provider.

Europe:

EC REP iHealthLabs Europe SARL www.ihealthlabs.eu
3 Rue Tronchet, 75008, Paris, France

+33(0)1 44 94 04 81 (9:00 AM-5:30 PM, Monday to Friday except holidays)
Email: support@ihealthlabs.eu

ANDON HEALTH CO., LTD.
No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China
Tfno.: +86-22-60526161

EXPLANATION OF SYMBOLS

IVD In vitro diagnostic medical device

SN Serial number

Caution, consult accompanying documents

Consult instructions for use

Manufacturer

Environmental Protection – Electrical products waste should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

EC REP Authorized representative in the European Community

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES

Keep away from rain

LOT Batch code

Use by date

STERILE R Sterilized Using Irradiation

Do not Reuse

CE 0197 Complies with IVD98/79/EC requirements

IMPORTANT INFORMATION REQUIRED BY THE FCC

Changes or modifications not expressly approved by iHealth Lab Inc. would void the user's authority to operate the product.

NOTE: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- —Reorient or relocate the receiving antenna.
- —Increase the separation between the equipment and receiver.
- —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- —Consult the dealer or an experienced radio/TV technician for help.

This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 du Canada.

V2.0